HE UNITED STATES PATENT AND TRADEMARK OFFICE Kathleen M. Miller et al. 10/789,398 Application No.: Date Filed: 02/27/2004 Implantable Or Insertable Medical Device Resistant To Microbial Title: Growth And Biofilm Formation Examiner: Unassigned Group Art: 3738 Docket: 98-P0151US2 INFORMATION DISCLOSURE STATEMENT (IDS) Mail Stop Missing Parts Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450 SIR: In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office. I. A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith. Any patents, publications or other information which are listed on PTO/SB/08 which are ъ.⊠ not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120: U.S. Serial Number U.S. Filing Date 02/08/2002 10/071,840 CONCISE EXPLANATION OF THE RELEVANCE (check at least one box) II. Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required). A concise explanation of the relevance of all patents, publications or other information ъ. 🔲 listed that is not in the English language is as follows: The following additional information is provided for the Examiner's consideration:

c. 🔲

III. CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.

Filing Date

Art Unit

# **FEES**

IV. 🛛	THIS II a.□	os is being filed under 37 C.F.R. §1.97(b): (check one box) within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is
	b. 🗌	required. within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
	c.🛛	before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
	d.	before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
v. 🗆	before t	OS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box) the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of the current of the current of the conference of the current of the conference of the current of the c
	ъ. 🔲	§1.17(p). See the statement below. No fee is required.
VI. 🗌		OS IS BEING FILED UNDER 37 C.F.R. §1.97(d): efore payment of the issue fee and is accompanied by the following: a statement under 37 C.F.R. §1.97(e) as provided below; and charge deposit account 50-1047 the petition fee set forth in §1.17(p).
VII. 🔲		MENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)
	a. □	dersigned hereby states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months
	b. <u></u>	prior to the filing of IDS; or no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
	с.	some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
VIII.	PAYM	ENT OF FEES  A check in the amount of is enclosed for the above-identified fee(s).
		Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
	$\boxtimes$	If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
		Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted, Mayer Fortkort & Williams, PC

Mayer Fortkort & Williams,	PC
Customer Number 27774	

David B. Bonham
Attorney for Applicant
Reg. No. 34,297
Tel. 703-433-0510

Enclosures:	$\boxtimes$	PTO/SB/0	8
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•	2.	4,240,163	12/23/80	Galin		3	13		
	3.	4,472,327	9/18/84	Neefe		264	1.9		
	4.	4,603,152	7/29/86	Laurin	et al.	604	265		
	5.	4,723,950	2/9/88	Lee		604	322		
	6.	4,731,080	3/15/88	Galin		623	6		
	7.	4,853,978	8/8/89	Stockur	n	2	167		
	8.	4,902,503	2/20/90	Umemu	ra et al.	424	83		
	9.	4,923,450	5/8/90	Maeda	et al.	604	265		
	10.	4,933,178	6/12/90	Capelli		424	78		
	11.	4,946,899	8/7/90	Kenned	y et al.	525	244		
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	1.	WO 97/14447	4/24/97	PCT		A61L 27	00	1	
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		Swartz, R., et al., "Biofi Vol. 37, no. 4, OctDec.	lm Formation on 1991, pp. 626-63	Peritonea 4.	l Catheters Does Not Requ	ire the Prese	nce of Infection	ı," <i>ASAI0</i>	Trans.,
		Richards, G.K., et al., "	Comparative Rat	es of Antil	biotic Action Against <i>Staph</i>	ylococcus ep	idermidis Biofi	lms," <i>ASA1</i>	O Trans
		Vol. 37, no. 3, JulSept.	1991, pp. M160-	162.		- F			- 1
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	12.	4,978,391	12/18/90	Jones		106	35		
	13	5,080,892	1/14/92	Yaman	ori et al.	424	78.09		
	14.	5,091,205	2/25/92	Fan		427	2		
	15.	5,091,442	2/25/92	Milner		523	122		
	16.	5,098,379	3/24/92	Conwa	y et al.	604	51		
	17.	5,102,401	4/7/92	Lambe	rt et al.	604	264		
	18.	5,102,402	4/7/92	Dror et	al.	604	265		
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	21.	5,137,671	8/11/92	Conwa	y et al.	264	130		
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		Stamm, Walter E., "Ca Journal of Medicine, Vo	theter-Associated ol. 91, no. 3B, Sep	l Urinary ' ot. 1991, p	Tract Infections: Epid p. 65S-71S.	lemiology, Pathoger	iesis, and Prev	ention,"Ai	merican
		Golomb, Gershon, et al Agent," Journal of Biol	., "Prevention of medical Materials	Bacterial Research	Colonization on Polyu , Vol. 25, no. 8, Aug. 1	rethane <i>in vitro</i> by 991, pp. 937-952.	Incorporated	Antibacter	ial
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	22	5,165,952	11/24/92	Solomon et al.	427	2		
	23.	5,171,318	12/15/92	Gibson et al.	623	5		
	24.	5,178,870	1/12/93	Schaeken et al.	424	405		
	25.	5,217,493	6/8/93	Raad et al.	623	11		
	26.	5,261,896	11/16/93	Conway et al.	604	265		
	27.	5,272,012	12/21/93	Opolski	428	423.1		
	28.	5,304,121	4/19/94	Sahatjian	604	53		
	29.	5,328,954	7/12/94	Sarangapani	524	589		
	30.	5,344,411	9/6/94	Domb et al.	604	265		
	31.	5,360,415	11/1/94	Yabushita et al.	604	265		
	32.	5,362,754	11/8/94	Raad et al.	514	566		
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		Mulhall, Anne, "Biofil	ms and Urethral (	Catheter Infections," Nursing Stand	lard, Vol. 5, no.	18, Jan. 23-29	), 1991, рр.	26-28.
		•	al., "Effect of <i>Sta</i>   Methacrylate (P   284-288.	phylococcus epidermidis on Adhere MMA) and Gentamicin-Containing	nce of <i>Pseudom</i> PMMA," <i>Jou</i>	onas aerugino rnal of Orthop	sa and Pro aedic Resec	teus irch,

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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ATTY DOCKET NO.	SERIAL NO.
98-PO151 US2	10//7/89,398
Kathleen M. Miller et al.	

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	,		U.S	. PATENT	DOCUMENTS				
*EXAMINER		DOCUMENT NUMBER	DATE	_	NAME	CLASS	SUBCLASS	FILING DATI	
	44.	5,679,399	10/21/97	Shlenker et al.		427	2.3		
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		OTHER DOCUMEN	ITS (Includin	g Author,	Title, Date, Pertin	ent Pages, Etc.	 )	<u>                                      </u>	
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Docket Number (Optional) 98-PO151 US 2	Application Number 10/789, 398
Applicant(s) Kathleen M. Miller et al.	
Filing Date	Group Art Unit

			ruing Date	02/27/04	3738		
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Docket Number (Optional)	Application Number
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Applicant(s) Kathleen M. Miller	
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				Application Number	10/789,398	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	02/27/04	
				First Named Inventor	Kathleen M. Miller et al.	
				Group Art Unit	3738	
(use as many sheets as necessary)				Examiner Name	Unassigned	
Sheet	ı	of	1	Attorney Docket Number	98-PO151 US 2	

Examiner	Cite No. 1	U.S. Patent Document Number Class/Subclass		Name of Patentee or Applicant	Date of Publication of Cited Document MM-
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	54	2001/0010016 A1	623/1.42	Modak et al.	07/26/2001
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Initials*	No. '	Office <sup>3</sup>	Number *	Class/Subclass	Applicant of Cited Document	MM-DD-YYYY	
	3	EP	0 328 421 A2	A61 L 29/00	Trustees of Columbia University in the City of New York	08/16/1989	
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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>1</sup> For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>3</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

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Docket Number (Optional)	Application Number	
98-PO151US2	10/789,398	
Applicant(s) Kathleen M. Miller et al.		
Filing Date 02/27/04	Group Art Unit	

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	<b>,</b> ,			U.S. PATENT DOCUMENTS			
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			<u> </u>	OTHER DOCUMENTS (Inc	cluding Author, Title, De	ate. Pertinent Pa <sub>l</sub>	es. Etc.)
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